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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,254	09/26/2005	Manuela Villa	17719 (PC27263A)	1404

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EXAMINER  
RAHMANI, NILOOFAR

ART UNIT 1625	PAPER NUMBER
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MAIL DATE 05/10/2007	DELIVERY MODE PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/522,254

Applicant(s)

VILLA ET AL.

Examiner

Niloofar Rahmani

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-29 are pending in the instant application and claim 30 is cancelled.

#### *Priority*

2. This application is filed on 09/26/2005, which is a 371 of PCT/EP03/07000, filed on 07/01/2001, which claims benefit of 60/398,122, filed on 07/25/2002.

3. The rejection of claim 30 under 35 U.S.C. 101 and 35 U.S.C. 112, second paragraph is withdrawn in view of the cancellation of the claim.

4. The rejection of claims 19-20 and 24 under 35 U.S.C. 112, first and second paragraph for "diazotation, subsequent appropriate quenching, suitable solid support" is maintained for reason of record. Applicants argue that "diazotation" means reacting primary aryl amines with nitrous acid to make a diazonium ion. And "quench" refers to a rapid cooling process. Applicants also submit that the type of solid support is well known and how such supports react with formula (I) to form formula (III) is fully supported by the specification. It is the examiner's position that "diazotation" of all primary aryl amines are not described nor enabled by the instant application. Applicants do not enable how to diazotate and subsequent quench formula (II) to a compound of formula (I). There are multiple ways to rapidly cool something. For example, put in freezer or using ice. The only written description for "solid support" is on page 26, lines 1-14. it does

not have written description and enablement for other solid support other than on page 26.

5. The rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reason of record. Applicants argue that there is sufficient support in the specification to enable a person with ordinary skill in the art to make and/or use the invention. It is the examiner's position that the pharmacological results illustrated on pages 32-40 appeared to be the results in vitro assays only. There are no results for real world treatment of cancer, viral infection, Alzheimer's, etc. therefore, the 112, first rejection is maintained.

6. The rejection of claims 1-18, 21-23, and 25-29 under 35 U.S.C. 102(b) is maintained for reason of record. Applicants argue that claims 1-12 are directed to a method of treating diseases caused by and/or associated with an altered protein kinase activity, using compound of formula (I). The cited compound in Winters possesses cardiotonic, antihypertensive, CNS depressant, neuroleptic, and analgesic activity. It is the examiner's position that neurodegenerative disorder in the instant application can encompassed antipsychotic agent, autoimmune diseases in the instant application can encompassed CNS, neuroleptic, cardiotonic, antihypertensive. Therefore, the instant claims are anticipated by Winters et al.

7. The objection of claim 29 is maintained because claim 29 is claiming a compound. If applicant wishes to change the claim to a compound of a use, it is suggested that claim 29 to be a method of treat.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR

Art Unit: 1625

only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

05/07/2007

NR



DMARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625